CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

Trichoderma harzianum

Chemical Code # 4016, Tolerance # 52077

4/9/99

I. DATA GAP STATUS

Chronic toxicity, rat:	No study on file; not required at this time[1]
Chronic toxicity, dog:	No study on file; not required at this time[1]
Oncogenicity, rat:	No study on file; not required at this time[1]
Oncogenicity, mouse:	No study on file; not required at this time[1]
Reproduction, rat:	No study on file; not required at this time[1]
Teratology, rat:	No study on file; not required at this time[1]
Teratology, rabbit:	No study on file; not required at this time[1]
Gene mutation:	No study on file; not required at this time[1]
Chromosome effects:	No data gap; no adverse effect
DNA damage:	No study on file; not required at this time[1]
Neurotoxicity:	No study on file; not required at this time[1]

Toxicology one-liners are attached.

All record numbers through 143243 were examined.
** indicates an acceptable study.
Bold face indicates a possible adverse effect.
indicates a study on file but not yet reviewed.
File name: T175578
Leung, 4/9/99

[1] Toxicology data for *Trichoderma harzianum* have been submitted and reviewed as a microbial pesticide. Toxicity data requirements are set forth under a tiered system. These studies are not required at this time.

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

COMBINED, RAT

No study on file.

CHRONIC TOXICITY, RAT

No study on file.

CHRONIC TOXICITY, DOG

No study on file.

ONCOGENICITY, RAT

No study on file.

ONCOGENICITY, MOUSE

No study on file.

REPRODUCTION, RAT

No study on file.

TERATOLOGY, RAT

No study on file.

TERATOLOGY, RABBIT

No study on file.

GENE MUTATION

52077-021 141257 842 "TRICHODEX (Trichoderma harzianum): Assessment of Mutagenic Potential in Histidine Auxotrophs of Salmonella typhimurium (The Ames Test)" by K. May, Life Science Research Limited, Eye, Suffolk, England (report #93/MAK133/0471; 7/5/93). In a preliminary toxicity test, the TA 98 strain of S. typhimurium was exposed to up to 0.6 ml/plate of Trichoderma harzianum extract (prepared by subjecting a Trichodex/water mixture [1 g/2 ml] to high-shear mixing @ 20,000 rpm for 5 min followed by sonication for 30 min, centrifugation and filtration of the supernatant) in minimal agar for 2 days @ 37°C and the background lawn of non-revertant colonies was examined. The result indicated that while there was no thinning of the background lawn (interpreted as no toxicity), revertant colonies increased at 0.5 & 0.6 ml extract. It was suspected that this increase reflected the presence of histidine in the extract. The next expt. compared the S. typhimurium growth-promoting ability (measured in suspension by absorbance) of a 1:100 dilution of extract (0-125 ul) with that of histidine (0-50 ug/ml), showing in both cases that the relationship was linear. 1 ul of Trichodex extract/tube was calculated to be equivalent to 6.8 ug histidine/tube (thus the extract was considered to contain the equivalent of 6.8 mg/ml histidine). While direct assay of histidine in the extract was not performed, histidine contamination was considered the most likely explanation for the observed growth promotion.

The Ames assay is thus considered an inappropriate test of the ability of extract to induce mutation. **Supplemental.** (Rubin, 3/26/96)

CHROMOSOME EFFECTS

52077-013 141244 843 "TRICHODEX (Trichoderma harzianum): Mouse Micronucleus Test to Comply with O.E.C.D. Guideline 474 (1983)" by C.N. Edwards, Life Science Research Limited, Eye, Suffolk, England (report #93/MAK134/0154; 3/29/93). 5/sex/dose received 200, 1000 or 5000 mg/kg (i.e., up to $1.56x10^8$ cfu suspended in 0.5% methyl cellulose) by oral gavage (15 ml/kg) and were sacrificed 24 hr post dose. An additional 5/sex/dose/sacrifice time received 0 or 5000 mg/kg and were sacrificed 48 or 72 hr post dose. At least 2000 erythrocytes/ animal were examined from bone marrow smears for micronuclei and polychromatic:mature cell ratios (indicative of gross toxicity). Micronucleated polychromatic erythrocyte frequencies at all concentrations & sacrifice times were similar to controls. 30 mg/kg chlorambucil, the positive control, successfully induced micronuclei and suppressed the polychromatic:mature cell ratio in both sexes. Toxicity was not apparent. Under the present conditions, Trichodex does not induce micronuclei in mice, nor is it associated with bone marrow toxicity. **Acceptable.** (Rubin, 3/27/96)

DNA DAMAGE

No study on file.

NEUROTOXICITY

No study on file.